IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
BROWNSVILLE DIVISION

MARIA DEL VALLE *Plaintiff,* v. PLIVA, INC., TEVA PHARMACEUTICALS USA, INC., ENDO PHARMACEUTICALS HOLDINGS, INC.; and QUALITEST PHARMACEUTICALS, INC. *Defendants*	§ § § § § § § § § § § § § §	CIVIL ACTION NO. 11- Jury Trial Demanded

PLAINTIFF'S ORIGINAL COMPLAINT

TO THE HONORABLE U.S. DISTRICT JUDGE:

Plaintiff States:

1. PARTIES

1.01 Plaintiff Maria Del Valle (hereinafter referred to as "Ms. Del Valle" or "Plaintiff") is an individual who is a resident and citizen of Harlingen, Cameron County, Texas.

1.02 Defendant **ENDO PHARMACEUTICALS HOLDINGS, INC.,** (hereinafter referred to as "Endo") is a Delaware corporation with its principal place of business in Pennsylvania. Endo may be served with process through its Registered Agent, The Corporation Trust Company: Corporation Trust Center, 1209 Orange Street, Wilmington, New Castle County, Delaware, 19801.

1.03 Defendant **QUALITEST PHARMACEUTICALS, INC**. (hereinafter referred to as "Qualitest") is an Alabama corporation with a principal place of business in Alabama.

Qualitest regularly conducted business in Texas. Qualitest may be served with process by registered mail, return receipt requested, upon: William S. Propst, Sr., 301 Meridian Street, Suite 101, Huntsville, Alabama 35801.

1.04 Hereafter, Endo and Qualitest Pharmaceuticals, Inc. will be collectively referred to as "Endo."

1.05 Defendant **TEVA PHARMACEUTICALS USA, INC.** (hereinafter "Teva") is a Delaware corporation with its principal places of business in Pennsylvania. Defendant is a subsidiary or division of Teva Pharmaceuticals Industries, Ltd., a corporation organized, existing and doing business under and by virtue of the laws of Israel, headquartered in Petach Tikvah, Israel. Defendant may be served with process through its registered agent: Corporate Creations Network Inc., 3411 Silverside Road, Rodney Building #104, Wilmington, Delaware 19810.

1.06 Defendant **PLIVA, INC.** individually and f/k/a Sidmark Laboratories, Inc., is a New York corporation with its principal place of business in New Jersey. Defendant is a subsidiary or division of Pliva d.d., a corporation organized, existing and doing business under and by virtue of the laws of the Republic of Croatia, headquartered in Zagreb, Croatia. Pliva d.d. is a wholly owned subsidiary of Barr Pharmaceuticals LLC as a result of Barr's acquisition of Pliva in 2006. Barr Pharmaceuticals LLC was later acquired by co-Defendant Teva Pharmaceuticals USA, Inc. and is now a wholly owned subsidiary of TEVA. Pliva, Inc. may be served with process through its registered agent Corporate Creations Network Inc., 3411 Silverside Road, Rodney Building #104, Wilmington, Delaware 19810.

1.07 Endo, Pliva, and Teva are cumulatively referred to as "Defendants".

2. VENUE AND JURISDICTION

2.01 Both jurisdiction and venue are proper in the Southern District of Texas. The

Defendants conduct, or have conducted, business activity in Cameron County, Texas and the Defendants have distributed products throughout Cameron County, Texas. Ms. Del Valle was prescribed the Defendants' products, she purchased the Defendants' products, and she consumed the Defendants' products in the Southern District of Texas, Brownsville Division.

2.02 Jurisdiction is based on complete diversity between the Plaintiff and all the Defendants pursuant to 28 U.S.C. § 1332.

2.03 Venue is proper as to causes of action against all Defendants pursuant to 28 U.S.C. §1391.

2.04 This Court has personal jurisdiction over Defendants Endo, Pliva, and Teva because they, either directly or through an agent, regularly do or solicit business in Texas, engage in other persistent courses of conduct in Texas, and derive substantial revenue from services, or things used or consumed in Texas. Upon information and belief, at all relevant times, each of the Defendants, was present and doing business in the State of Texas. At all relevant times, each of the Defendants transacted, solicited, and conducted business in the State of Texas and derived substantial revenue from such business. At all relevant times, the Defendants expected or should have expected that each of their acts as alleged herein would have consequences within the United States of America and in the Southern District of Texas.

2.05 A substantial part of the causes of action accrued in the State of Texas because Ms. Del Valle received and consumed the Defendants' pharmaceutical products in the Southern District of Texas where she also sustained her injuries. Willacy County and Cameron County constitute the Southern District of Texas, Brownsville Division.

2.06 The amount in controversy exceeds $75,000.00.

3. STATEMENT OF FACTS

A. Ms. Del Valle Developed Tardive Dyskinesia after Ingesting Reglan/Metoclopramide

3.01 Plaintiff brings this action for the purpose of recovering damages for the personal injuries she has suffered as a result of being prescribed and ingesting Reglan, metoclopramide and/or metoclopramideHCl (hereinafter referred to as "Reglan/ metoclopramide").

3.02 At all times material hereto, Defendants Endo, Pliva, and Teva were engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties, as successor in interest, or other related entities Reglan/metoclopramide in the state of Texas and in interstate commerce.

3.03 At all relevant times, Defendants were acting by and through their agents, servants and/or employees, each of whom were acting within the scope and course of their employment by agency or authority on their behalf.

3.04 At all times relevant hereto, Defendants were in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, and/or advertising the pharmaceutical drugs known as Reglan/metoclopramide in the State of Texas and in interstate commerce.

3.05 In 2002, Ms. Del Valle's physician prescribed Reglan/metoclopramide at a dosage of 10mg, three to four times daily, to treat gastroesophageal reflux disease. Ms. Del Valle intermittently ingested Reglan/metoclopramide, as prescribed, for approximately eight years -- until one year ago after the movements started.

3.06 The active ingredient, metoclopramide and metoclopramide HCl, is a dopamine antagonist.

3.07 Upon information and belief, in prescribing the Reglan/metoclopramide to Ms. Del Valle on a long-term basis, her prescribing doctor relied upon information published in the

package inserts and/or the Physicians' Desk Reference (hereinafter referred to as "PDR") or otherwise disseminated by the Reference Listed Drug Company (hereinafter referred to as "RLD") and/or the New Drug Application Holder (hereinafter referred to as "NDA Holder").

3.08 Ms. Del Valle ingested the Reglan/metoclopramide as prescribed.

3.09 Ms. Del Valle used the pharmaceutical drug Reglan/metoclopramide without substantial change in the condition of the drugs between the time of design and manufacture of the drugs and the time he used the drugs as directed.

3.10 Ms. Del Valle's long-term ingestion of the Reglan/metoclopramide caused her injuries.

3.11 Ms. Del Valle was not aware of information different from or contrary to the inaccurate, misleading, materially incomplete, false and/or otherwise inadequate information disseminated in the PDR, RLD, or by the NDA Holders.

3.12 After ingesting Reglan/metoclopramide for many years, Ms. Del Valle began exhibiting abnormal movements, which have very recently been diagnosed as Tardive Dyskinesia.

3.13 Ms. Del Valle's use of Reglan/metoclopramide, as prescribed, resulted in overexposure to the drugs which have caused her to suffer serious, permanent and disabling injuries, including but not limited to, injuries of or associated with the central nervous and extrapyramidal motor systems, specifically Tardive Dyskinesia, a severe and often permanent disfiguring neurological movement disorder.

3.14 Ms. Del Valle's serious and permanent injuries, as described above, came about as a foreseeable and proximate result of Defendants' dissemination of inaccurate, misleading, materially incomplete, false and otherwise inadequate information concerning the potential

effects of exposure to and long-term ingestion of Reglan/metoclopramide to the medical community, Ms. Del Valle, and other foreseeable users of the drug.

3.15 Ms. Del Valle has experienced and will continue to experience medical and related expenses, loss of ability to provide household services, disfigurement, disability, pain, suffering, psychological injury and other injuries and damages due to the prescription and ingestion of this drug.

3.16 Recognizing the inadequate nature of the Defendants' label and warnings, in February 2009 the United States Food and Drug Administration (hereinafter referred to as "FDA") issued an advisory requiring the addition of a **Boxed Warning** for Reglan/metoclopramide. This new warning, appearing at the top of the label, spells out that "Chronic treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible ...". Additionally, the new Boxed Warning now tells physicians and patients that "Prolonged treatment (greater than 12 weeks) with metoclopramide should be avoided in all but rare cases ...". Finally, the FDA is now requiring that manufacturers/Defendants implement a Risk Evaluation and Mitigation Strategy because the FDA has determined that the use of Reglan/metoclopramide "pose[s] a serious and significant public health concern requiring the distribution of a Medication Guide." This Medication Guide, setting out all the risks of the drug and to be given to all users "is necessary for the patients' safe use of Reglan (metoclopramide)...". Unfortunately, neither this Boxed Warning nor the Medication Guide was available to Ms. Del Valle.

B. Defendants' Wrongful Conduct

3.17 This case involves Defendants' failure to warn doctors and patients of information within their knowledge or possession which indicated that the subject Reglan/metoclopramide,

when taken for long periods of time, caused serious, permanent and debilitating side effects, including tardive dyskinesia.

3.18 Defendants jointly and severally marketed, manufactured and distributed Reglan/metoclopramide and encouraged the long-term use of these drugs, misrepresented the effectiveness of these drugs and concealed the drug's dangerous side effects.

3.19 Reglan/metoclopramide is indicated only as short-term therapy for symptomatic gastroesophageal reflux and acute and recurrent diabetic gastric stasis.

3.20 Reglan/metoclopramide is indicated only for use for no greater than 12 weeks; however, Defendants represented that Reglan/metoclopramide was safe for use to treat nausea and/or esophageal reflux for durations that exceed 12 weeks.

3.21 Patients who use Reglan/metoclopramide for long periods are at a significantly increased risk of developing a severe and permanent neurological movement disorder.

3.22 Other serious side effects caused by ingesting Reglan/metoclopramide for long periods include, but are not limited to, central nervous system disorders, depression with suicidal ideation, akathesia, tardive dyskinesia, tardive dystonia, visual disturbances and interference with drug metabolism.

3.23 Patients who use Reglan/metoclopramide for long periods who are not able to effectively metabolize it are at a greater risk of developing these serious and permanent injuries.

3.24 Tardive dyskinesia, one of the serious side effects associated with the ingestion of Reglan/metoclopramide is a debilitating neurological disorder that often results in involuntary and uncontrollable movements of the head, neck, face, arms, legs and trunk, in addition to facial grimacing, uncontrollable tongue movements and other involuntary movements. Presently, there is no cure for tardive dyskinesia.

3.25 Ms. Del Valle's diagnosed tardive dyskinesia, caused by the ingestion of metoclopramide, is permanent.

3.26 Defendants Qualitest, Pliva, and Teva expressly warranted to physicians that Reglan/metoclopramide was safe for long-term use.

3.27 Defendants Qualitest, Pliva, and Teva knew that its warranties regarding safety for long-term use would be relied upon by ordinary, reasonable and prudent physicians who would share that information with other physicians in their communities and that eventually physicians would come to rely on Defendants' express warranties about Reglan/metoclopramide's safety for long-term use.

3.28 Defendants Qualitest, Pliva, and Teva's express warranties about the safety of Reglan/metoclopramide for long-term use were false and intentionally and negligently misleading.

3.29 As successor-in-interest to Qualitest Pharmaceuticals, Inc., Endo is legally responsible for the conduct, fraudulent and negligent acts, intentional and willful omissions, and misleading representations and warranties made by Qualitest Pharmaceuticals, Inc. concerning the safety and adequacy of Reglan/metoclopramide, and all liabilities stemming therefrom.

3.30 Defendants Endo purchased from Qualitest Pharmaceuticals, Inc. the rights and liabilities associated with Reglan/metoclopramide, the terms of which, upon information and belief, obligated Endo to be responsible for claims related to the ingestion or use of Reglan/metoclopramide.

3.31 Defendants Endo, Pliva, and Teva knew that they must fully disclose material safety data and information regarding a new drug's chemistry, proposed manufacturing process, proposed model labeling, including warnings about risks and side effects, and test results

involving animal studies, clinical studies, and the drug's bioavailability.

3.32 Endo, Pliva, and Teva knew that the data and information would be relied upon by the medical community, physicians, Plaintiff and other foreseeable users of Reglan/metoclopramide once the NDA was approved and Endo, Pliva, and Teva were listed as the Reference Listed Drug Company for the drug.

3.33 Endo, Pliva, and Teva intentionally and negligently disseminated misleading information to physicians across the country, through the PDR, about the risks of long-term ingestion of Reglan/metoclopramide and the increased risk of extrapyramidal side effects, including tardive dyskinesia.

3.34 Under the FDA scheme, Endo, Pliva, and Teva were the NDA Holders and/or Reference Listed Drug Companies (RLD), under a specific NDA, for Reglan/metoclopramide.

3.35 At all times material hereto, Defendants Endo, Pliva, and Teva, as the NDA Holder and/or RLD companies, were aware of the serious side effects caused by Reglan/metoclopramide including, but not limited to, central nervous system disorders, depression with suicidal ideation, akathesia, tardive dyskinesia, visual disturbances and interference with drug metabolism.

3.36 Defendants Endo, Pliva, and Teva have a duty to ensure their warnings to the medical community are accurate and adequate, to conduct safety surveillance of adverse events for the drug, and to report *any* data related to the safety and/or accuracy of the warnings and information disseminated regarding the drug.

3.37 Defendants Endo, Pliva, and Teva represented that Reglan/metoclopramide was safe for use to treat gastritis/gastroesophageal reflux knowing that the drug was not safe for that purpose and was dangerous to the health and body of Ms. Del Valle.

3.38 Defendants Endo, Pliva, and Teva represented that Reglan/metoclopramide caused minimal side effects knowing that the drug caused central nervous system side effects, and extrapyramidal symptoms, among other side effects, far more frequently than represented.

3.39 Defendants Endo, Pliva, and Teva had actual knowledge, through their own studies and studies by independent investigators, that doctors frequently prescribed Reglan/metoclopramide for long-term use that was not safe for patients.

3.40 Defendants Endo, Pliva, and Teva had actual knowledge, through their own studies and studies by independent investigators, that nearly one-third of all patients who used Reglan/metoclopramide received it on doctor's prescriptions for 12 months or longer, rather than 12 weeks or less.

3.41 Defendants Endo, Pliva, and Teva also had actual knowledge, through research by independent investigators, that the risk of tardive dyskinesia and other extrapyramidal side effects of Reglan/metoclopramide in patients who receive the drug for 12 weeks or longer is approximately 100 times greater than disclosed in package inserts and the PDR.

3.42 Defendants Endo, Pliva, and Teva knew, or through the exercise of reasonable care should have known, that many patients who use Reglan/metoclopramide are not able to effectively metabolize it and that as a foreseeable consequence of their inability to effectively metabolize, those patients have a greater risk of developing serious and permanent injuries.

3.43 Defendants Endo, Pliva, and Teva had actual knowledge of facts which demonstrated that representations in the Reglan/metoclopramide package insert, the PDR and literature they distributed to physicians were false and misleading.

3.44 Defendants Endo, Pliva, and Teva failed to correct their monograph and/or disclose that knowledge to the medical community, Plaintiff, and other foreseeable users.

3.45 It is the public policy of the United States and of this state, as reflected in the Hatch-Waxman Act, to encourage the availability of cheaper, generic drug products that are therapeutically equivalent to name brand products and to encourage the substitution, as appropriate, of such generic products for name brand products in patients' medical therapy.

3.46 Defendants Endo, Pliva, and Teva, as prescription drug manufacturers and/or distributors, knew or should have realized that so-called "drug product selection laws," enacted in every state, including this state, authorize or require a prescription for a drug identified by product brand name or by generic name to be filled, subject to certain limitations, with a generic drug product that is therapeutically equivalent to the name brand drug product.

3.47 Defendants Endo, Pliva, and Teva knew or ought to have realized that generic drug manufacturers customarily copy verbatim the package insert for the name brand prescription drug product to give the impression that the information contained in the package inserts accompanying their own generic prescription drugs is accurate and not misleading.

3.48 Defendants Endo, Pliva, and Teva knew or ought to have known that the generic drug manufacturers also typically rely upon the marketing efforts of the name brand manufacturer to generate sales of their own products.

3.49 Defendants Endo, Pliva, and Teva knew or ought to have realized that physicians commonly consult the information disseminated by the name brand manufacturer, in the PDR or otherwise, and rely upon that information in their decisions concerning the prescribing of those products for their patients.

3.50 Defendants Endo, Pliva, and Teva knew or should have known, specifically, that physicians would rely upon the information disseminated to them by the name brand manufacturer, regardless of whether the prescriptions might be filled with either the name brand

product, Reglan, or generic Reglan/metoclopramide, and that many patients, in accordance with those prescriptions, would be likely to ingest generic Reglan/metoclopramide.

3.51 Defendants Endo, Pliva, and Teva submitted an Abbreviated New Drug Application (ANDA) to the FDA, based on representations made by the RLD companies, requesting permission to manufacture, market, and distribute generic Reglan/metoclopramide.

3.52 Under the ANDA process, the Code of Federal Regulations required Endo, Pliva, and Teva to submit a label for Reglan/metoclopramide initially identical in all material aspects to the reference listed drug label.

3.53 Under the Code of Federal Regulations, Endo, Pliva, and Teva had a duty to ensure their Reglan/metoclopramide warnings to the medical community were accurate and adequate, to conduct post market safety surveillance, to review all adverse drug event information, and to report any information bearing on the risk and/or prevalence of side effects caused by Reglan/metoclopramide.

3.54 Under the Code of Federal Regulations, if Endo, Pliva, or Teva discovered information in the course of the fulfillment of its duties as outlined above, it must report that information to the medical community, Plaintiff and other foreseeable users of Reglan/metoclopramide to ensure that its warnings are continually accurate and adequate.

3.55 Defendant Endo, Pliva, and Teva failed to investigate the accuracy of its metoclopramide and/or metoclopramide HCl drug labels.

3.56 Defendant Endo, Pliva, and Teva failed to review the medical literature for the metoclopramide drug and/or metoclopramide HCl drug.

3.57 Defendants Endo, Pliva, and Teva relied upon the name brand manufacturer and the referenced listed drug companies to review the aforementioned medical literature for

Reglan/metoclopramide.

3.58 Under the FDA scheme, if the FDA approves a label change as requested by an ANDA holder, the NDA holder (also referred to as the RLD company) must also amend its label.

3.59 Defendant Endo, Pliva, and Teva failed to communicate the true and accurate risks and/or prevalence of severe neurological side effects resulting from the ingestion of drugs containing Reglan/metoclopramide.

3.60 Defendants disseminated to physicians, through package inserts, the publication of the PDR, and otherwise, information concerning the properties and effects of Reglan/metoclopramide, with the intention that physicians would rely upon that information in their decisions concerning the prescription of drug therapy for their patients.

3.61 Defendants knew, or should have known through the exercise of reasonable care, that the package insert for Reglan/metoclopramide substantially understated the prevalence of acute and long-term side effects on ingesting the drug.

3.62 Defendants failed to use reasonable care to modify the package insert to adequately warn physicians about the true risks of both short-term and long-term use, even after several injured patients filed lawsuits alleging inadequate warnings and produced competent expert testimony supporting their allegations.

3.63 Defendants owed a duty in all of their several undertakings, including the dissemination of information concerning Reglan/metoclopramide, to exercise reasonable care to ensure that they did not create unreasonable risks of personal injury to others.

3.64 Reglan/metoclopramide was widely advertised by Defendants as a safe and effective treatment of diabetic gastroparesis, gastroesophageal reflux disease (GERD) and other gastrointestinal disorders.

3.65 Defendants failed to conduct and report post market safety surveillance on Reglan/metoclopramide.

3.66 Defendants failed to review all adverse drug event information[1] and to report any information bearing upon the adequacy and accuracy of their warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Reglan/metoclopramide.

3.67 Defendants failed to monitor all relevant scientific literature related to Reglan/metoclopramide.

3.68 Defendants failed to disclose material safety information regarding the serious and permanent side effects caused by taking Reglan/metoclopramide for long periods of time.

3.69 Defendants failed to report data, *regardless of the degree of significance,* regarding the adequacy and/or accuracy of their warnings, efficacy or safety of Reglan/metoclopramide.

3.70 Defendants knowingly concealed from physicians material facts bearing on the interpretation of package insert disclosures that exposure to Reglan/metoclopramide can lead to tardive dyskinesia and other extrapyramidal side effects, that the risk is "believed" to increase with duration of therapy and total cumulative dose, and that therapy for longer than 12 weeks "cannot be recommended."

3.71 Defendants concealed the fact that Reglan/metoclopramide is a neuroleptic agent and dopamine antagonist, which can be expected to lead to tardive dyskinesia and other extrapyramidal side effects with approximately the same high frequency, particularly in longer term use, as other neuroleptic drugs and that epidemiological studies have consistently confirmed

[1] Defendants are required to review all adverse drug experience information obtained or otherwise received . . . from any source . . . including derived from postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports from the scientific literature, and unpublished scientific reports. 21 C.F.R. § 317.80(b).

this expectation.

3.72 Defendants also concealed the fact that the treatment of chronic or intermittent gastroesophageal reflux and/or diabetic gastroporesis and/or other gastric disorders with Reglan/metoclopramide for longer than 12 weeks is unlikely to be reasonably safe.

3.73 Some or all of the Defendants, as a result of their participation as defendants in previous litigation concerning Reglan/metoclopramide products received clear notice of the suppression of important safety information concerning Reglan/metoclopramide, yet despite this notice chose to ignore the information and join consciously in the suppression.

4. CLAIMS FOR RELIEF

A. Negligence

4.01 Plaintiff restates each and every preceding allegation of the Complaint and incorporates each by reference as though set forth fully.

4.02 Defendants owed a duty to the general public and specifically to Plaintiff to exercise reasonable care in the design, study, development, manufacture, promotion, sale, marketing and distribution of their prescription medications, including the Reglan/metoclopramide at issue in this lawsuit. Defendants failed to exercise reasonable care in the design of Reglan/metoclopramide because as designed, it was capable of causing serious personal injuries such as those suffered by Ms. Del Valle during foreseeable use. Defendants also failed to exercise reasonable care in the marketing of Reglan/metoclopramide because they failed to warn that, as designed, Reglan/metoclopramide was capable of causing serious personal injuries such as those suffered by Plaintiff during foreseeable use.

4.03 Defendants breached their duty and were negligent in their actions, misrepresentations, and omissions toward Plaintiff in that Defendants:

a. Failed to use due care in developing, testing, designing and manufacturing Reglan/metoclopramide so as to avoid the aforementioned risks to individuals when Reglan/metoclopramide was being used for treatment of patients;

b. Failed to accompany their product with proper or adequate warnings regarding adverse side effects and health risks associated with the use of Reglan/metoclopramide and the comparative severity and duration of such adverse effects;

c. Failed to accompany their product with proper or adequate rate of incidence or prevalence of permanent irreversible neurological damage;

d. Failed to provide warnings that accurately reflected the symptoms, scope or severity of the side effects and health risks;

e. Failed to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Reglan/metoclopramide;

f. Failed to provide adequate training or information to medical care providers for appropriate use of Reglan/metoclopramide;

g. Failed to adequately warn consumers and medical prescribers (but instead actively encouraged the sale of Reglan/metoclopramide), about the following: (1) that Reglan/metoclopramide should not be prescribed for more than 12 weeks; (2) that Reglan/metoclopramide can cause neuromuscular side effects, including, but not limited to, tardive dyskinesia; (3) that Reglan/metoclopramide should be discontinued in the face of involuntary facial, tongue, jaw, limb or trunk movements; and (4) that the health risks posed by Reglan/metoclopramide may become debilitating, difficult, and painful, necessitating lengthy and/or repeated visits to the doctor, clinic, or hospital;

h. Failed to adequately test and/or warn about the use of Reglan/metoclopramide, including, without limitation, the possible adverse side effects and health risks caused by the use of Reglan/metoclopramide;

i. Failed to adequately warn users, consumers and physicians about the severity, scope and likelihood of neurological damage and related dangerous conditions to individuals taking Reglan/metoclopramide; and Representing to physicians, including but not limited to Ms. Del Valle's prescribing physician, that this drug was safe and effective for use.

4.04 The Reglan/metoclopramide was in substantially the same condition when it was ingested by Ms. Del Valle as it was in when it left the control of Defendants. Reglan/metoclopramide's capability to cause serious personal injuries and damages such as those suffered by Plaintiff was not due to any voluntary action or contributory negligence of Plaintiff. The Reglan/metoclopramide was consumed by Ms. Del Valle as directed and without change in

its form or substance.

4.05 Defendants' failure to exercise reasonable care in the design and/or marketing of Reglan/metoclopramide was a proximate and producing cause of Plaintiff's injuries and damages. Plaintiff seeks all damages to which he may be justly entitled.

B. Strict Liability

4.06 Plaintiff restates each and every preceding allegation of the Complaint and incorporates each by reference as though set forth fully.

4.07 Plaintiff claims that Defendants are liable under the theory of strict products liability. Defendants were at all times relevant to this suit, and now are, engaged in the business of designing, manufacturing, testing, marketing, and placing into the stream of commerce pharmaceuticals for sale to, and use by, members of the public, including the Reglan/metoclopramide at issue in this lawsuit. The Reglan/metoclopramide manufactured by Defendants reached Ms. Del Valle without substantial change and was ingested as directed. The Reglan/metoclopramide was defective and unreasonably dangerous when it entered into the stream of commerce and when used by Ms. Del Valle.

4.08 Reglan/metoclopramide was unreasonably defective in design and marketing, considering the utility of the product and the risk involved in its use, because as designed and marketed, Reglan/metoclopramide could cause injuries such as those suffered by Ms. Del Valle during foreseeable use. This fact was known to Defendants at the time Reglan/metoclopramide was placed into the stream of commerce, but was not readily recognizable to an ordinary consumer, including Plaintiff. Nonetheless, Defendants failed to warn that Reglan/metoclopramide as designed and marketed was capable of causing serious personal injuries such as those suffered by Plaintiff during

foreseeable use. Such a failure to warn rendered the Reglan/metoclopramide unreasonably dangerously defective as designed and marketed.

4.09 The defective and unreasonably dangerous design and marketing of Reglan/metoclopramide was a direct, proximate and producing cause of Plaintiff's injuries and damages. Under strict products liability theories set forth in RESTATEMENT (SECOND) OF TORTS, Defendants are liable to Plaintiff for all damages claimed in this case, including punitive damages.

C. Breach of Warranty – Merchantability

4.10 Plaintiff restates each and every preceding allegation of this Complaint and incorporates each by reference as though set forth in full herein.

4.11 Defendants were at the time of the acts forming the basis of this lawsuit, and now are, merchants with respect to the Reglan/metoclopramide at issue in this lawsuit. Defendants have impliedly warranted to the public generally and specifically to Plaintiff that Reglan/metoclopramide was merchantable and fit for safe use for gastrointestinal relief, the purpose for which Defendants marketed Reglan/metoclopramide. Reglan/metoclopramide was not merchantable as warranted because, as designed, Reglan/metoclopramide was capable of causing serious personal injuries such as those suffered by Plaintiff during foreseeable use. Therefore, Defendants have breached the implied warranty of merchantability with respect to Reglan/metoclopramide.

4.12 As a direct and proximate result of Defendants' breach of the warranty of merchantability, Plaintiff sustained serious and permanent injuries and damages.

D. Breach of Warranty – Fitness for a Particular Purpose

4.13 Plaintiff restates each and every preceding allegation of this Complaint and

incorporates each by reference as though set forth in full herein.

4.14 Defendants knew that consumers such as Plaintiff would require Reglan/metoclopramide for safe use for gastrointestinal relief, and that consumers would rely on Defendants' skill and judgment to select suitable medications. Defendants provided such skill and judgment by marketing and selling Reglan/metoclopramide for that purpose. Plaintiff relied on Defendants' skill and judgment when selecting and purchasing the Reglan/metoclopramide at issue. The Reglan/metoclopramide used by Ms. Del Valle was not fit for its particular purpose because, as designed, Reglan/metoclopramide was capable of causing serious personal injuries such as those suffered by Plaintiff during foreseeable use. Therefore, Defendants have breached the implied warranty of fitness for a particular purpose with respect to Reglan/metoclopramide.

4.15 As a direct and proximate result of Defendants' breach of the warranty of merchantability, Plaintiff sustained serious and permanent injuries and damages.

E. Misrepresentation, Suppression of Evidence and Fraud

4.16 Plaintiff restates each and every preceding allegation of this Complaint and incorporates each by reference as though set forth in full herein.

4.17 Defendants committed actual fraud by making material representations, which were false, knowing that such representations were false and/or with reckless disregard for the truth or falsity of such representations, with the intent that Plaintiff rely on such material representations; Plaintiff acted in actual and justifiable reliance on such material misrepresentations and were injured as a result.

4.18 In addition, and in the alternative if necessary, Defendants knowingly omitted and downplayed material information, which omission constitutes a positive misrepresentation of material fact, with the intent that Plaintiff rely on Defendants' misrepresentations; Plaintiff acted

in actual and justifiable reliance on Defendants' representations and were injured as a result.

4.19 Defendants committed constructive fraud by breaching one or more legal or equitable duties owed to Plaintiff relating to the Reglan/metoclopramide at issue in this lawsuit, said breach or breaches constituting fraud because of their propensity to deceive others or constitute an injury to public interests or public policy.

4.20 Defendants misrepresented to the FDA, Plaintiff, and the health care industry the safety and effectiveness of Reglan/metoclopramide and/or fraudulently, intentionally and/or negligently concealed material information, including adverse information regarding the safety and effectiveness of Reglan/metoclopramide.

4.21 Defendants made these misrepresentations and actively concealed adverse information at a time when the Defendants knew, or should have known, that Reglan/metoclopramide had defects, dangers, and characteristics that were other than what Defendants had represented to Plaintiff and the health care industry generally. Specifically, Defendants misrepresented to and/or actively concealed from Plaintiff and the consuming public that:

a. Reglan/metoclopramide had statistically significant increases in neuromuscular side effects which could result in serious, permanent injury;

b. Reglan/metoclopramide had not been fully or adequately tested for use in excess of 12 weeks;

c. Patients on Reglan/metoclopramide should not take it more than 12 weeks;

d. Reglan/metoclopramide was not fully and adequately tested for the neuromuscular side effects.

4.22 The misrepresentations of and/or active concealment alleged were perpetuated directly and/or indirectly by Defendants. Defendants knew or should have known that these representations were false and made the representations with the intent or purpose that Plaintiff and/or her prescribing physicians would rely on them, leading to the use of

Reglan/metoclopramide. At the time of Defendants' fraudulent misrepresentations, Plaintiff and/or her prescribing physicians were unaware of the falsity of the statements being made and believed them to be true. Plaintiff and/or her prescribing physicians had no knowledge of the information concealed and/or suppressed by Defendants, and they justifiably relied on and/or were induced by the misrepresentations and/or active concealment and relied on the absence of safety information, which Defendants did suppress, conceal or failed to disclose, to Plaintiff's detriment.

4.23 Defendants had a post-sale duty to warn Plaintiff, her prescribing and treating physicians, and the public about the potential risks and complications associated with Reglan/metoclopramide in a timely manner. The misrepresentations and active fraudulent concealment by the Defendants constitute a continuing tort against Plaintiff, who purchased and/or ingested Reglan/metoclopramide. Defendants made the misrepresentations and actively concealed information about the defects and dangers of Reglan/metoclopramide with the intention and specific desire that Plaintiff and the consuming public would rely on such or the absence of information in selecting Reglan/metoclopramide as treatment.

4.24 As a direct and proximate result of the fraudulent acts and omissions, suppression and misrepresentation of Defendants, Plaintiff suffered significant and ongoing injuries and damages.

F. Deceptive Trade Practices

4.25 Plaintiff restates each and every preceding allegation of this Complaint and incorporates each by reference as though set forth in full herein.

4.26 Plaintiff purchased the Reglan/metoclopramide designed, manufactured, marketed, distributed and otherwise placed into the stream of commerce by Defendants, and is a

consumer as defined by the Deceptive Trade Practices-Consumer Protection Act, TEX. BUS. & COM. CODE ANN. § 17.45(4)(Vernon 2005), and applicable Texas case law. It is the purchase of these goods that forms the basis of Plaintiff's complaints.

4.27 Defendants have engaged in false, misleading and deceptive acts or practices as defined and proscribed by the Deceptive Trade Practices-Consumer Protection Act of Texas in the marketing, distribution and sale of the Reglan/metoclopramide at issue in this case. Specifically, Defendants have engaged in false, misleading, and deceptive acts and practices including, but not limited to, the following:

1. Causing confusion or misunderstanding as to the source, sponsorship, approval or certification of goods;
2. Representing that goods have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities which they do not have or that a person has a sponsorship, approval, status, affiliation, or connection which he does not;
3. Failing to disclose information concerning goods which was known at the time of the transaction if such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed;
4. Unconscionable actions and courses of action.

4.28 As a direct and proximate result of Defendants violation of the Texas Deceptive Trade Practices-Consumer Protection Act, Plaintiff suffered significant and ongoing injuries and damages.

5. GROSS NEGLIGENCE

5.01 Plaintiff restates each and every preceding allegation of the Complaint and incorporates each by reference as though set forth fully.

5.02 Plaintiff would further show that the negligent acts and/or omissions of Defendants, as set forth above, constitute an entire want of care so as to indicate that the acts and/or omissions in question were the result of conscious indifference and/or malice so as to give

rise to the award of exemplary damages.

5.03 Plaintiff would further show that the negligent acts and/or omissions of Defendants, as set forth above, constitute an act or omission,

a. which, when viewed objectively from the standpoint of Defendants, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to Plaintiff, and

b. of which Defendants had actual, subjective awareness of the risks involved, but nevertheless proceeded with conscious indifference to the rights, safety or welfare of Plaintiff.

5.04 The gross negligence of the Defendants was a proximate cause of the injuries and damages suffered by Plaintiff.

6. DAMAGES

6.01 As a producing and proximate result of the above-described acts and omissions of Defendants Teva Pharmaceuticals USA, Inc., Pliva, Inc., Qualitest Pharmaceutical, Inc., and Endo Pharmaceuticals, Inc., Individually and as a Successor to Qualitest Pharmaceutical, Inc., Plaintiff has incurred actual damages in excess of $75,000.00:

1. Reasonable and necessary medical expenses incurred in the past;

2. Reasonable and necessary medical expenses reasonably likely to be incurred in the future;

3. Conscious physical pain and suffering experienced in the past;

4. Conscious physical pain and suffering reasonably likely to be experienced in the future;

5. Mental anguish in the past;

6. Mental anguish likely to be experienced in the future;

7. Physical disfigurement in the past;

8. Physical disfigurement likely to be experienced in the future;

9. Physical impairment in the past;

10. Physical impairment likely to be experienced in the future;

11. Pre and post-judgment interest at the lawful rate;

12. Exemplary damages;

13. Damages contemplated by the Texas Deceptive Trade Practices-Consumer Protection Act, including attorneys' fees, costs and treble damages; and

14. Such other applicable damages as the Court deems appropriate.

7. DISCOVERY RULE

7.01 Plaintiff brings this suit within two (2) years of discovering MARIA DEL VALLE'S Reglan/metoclopramide-related conditions, or the existence of any Reglan/metoclopramide - related causes of action.

8. CPRC § 82.007 PRESUMPTION

8.01 Because Defendants withheld from and misrepresented to the United States FDA required information that was material and relevant to the performance of Reglan/metoclopramide and was causally related to Plaintiff's injuries, and in light of the holdings of *Wyeth v. Levine*, 555 U.S.____, 129 S.Ct. 1187 (2009), they are ineligible to take advantage of the presumption afforded by § 82.007 of the TEXAS CIVIL PRACTICE AND REMEDIES CODE.

9. PRAYER

WHEREFORE, Plaintiff MARIA DEL VALLE prays that upon final determination of these causes of action Plaintiff receives a judgment against Defendants PLIVA, INC., TEVA PHARMACEUTICALS USA, INC., QUALITEST PHARMACEUTICALS, INC., ENDO PHARMACEUTICALS HOLDINGS, INC.; Individually and as a Successor to QUALITEST PHARMACEUTICALS, INC., as follows:

1. Actual damages as alleged, jointly and/or severally against Defendants, in excess of $75,000.00;

2. Punitive damages alleged against Defendants, including Plaintiff's attorney fees, in excess of $75,000.00;

3. Costs of court and reasonable attorney fees necessary for preparation of this case for trial;

4. Prejudgment interest at the highest lawful rate allowed by law;

5. Interest on the judgment at the highest legal rate from the sate of judgment until collected; and

6. All such other and further relief at law and in equity to which Plaintiff may show himself to be justly entitled.

JURY TRIAL

Plaintiff hereby demands a trial by jury.

Respectfully submitted,

/s/ John Flood
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